K073017

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Kalamazoo, MI 49001
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NOV 3 0 2007

stryker
Instruments

510(k) Summary

Device Sponsor: Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001
(p) 269-323-7700
(f) 269-324-5412

Registration No.: 1811755

Trade Name: Stryker Steri-Shield Flyte Togas

Classification: Sterile Surgical Gowns

Equivalent to: K0063005-Stryker T6 Hoods and Togas

Device Description:

Device History

Summary of Stryker Steri-Shield Flyte Togas

The scope of this Special 510k material modification is limited to material changes to the gown. The toga has a hood and gown section. The hood covers the user's head. A lens is attached to the front of the hood. The gown of the toga covers the user's front, back and arms. The Stryker Steri-Shield Flyte Togas are tested to meet applicable AAMI PB70:2003 standards. The AAMI standard does not cover apparel for the head, face, and eyes. Therefore, the hoods and lens (components of the togas) are exempt from classification under the AAMI PB70:2003 standard.

Stryker Steri-Shield Flyte Toga, Pullover

The Stryker Steri-Shield Flyte Toga, Pullover is intended to be worn over any Stryker Flyte Helmet. The Stryker Steri-Shield Flyte Pullover togas provide Level 4 and Level 1 barrier protection for the critical zones as set froth in the accompanying drafted IFUs (Attachment 8 and as classified under the AAMI (Association for the Advancement of Medical Instrumentation) guidelines for barrier performance. This garment was tested for resistance to bacteriophage Phi-X174 in accordance with ASTM F1671:2003

per the AAMI Barrier Classification System and demonstrate a passing result with an AQL of 4% under Procedure A. Level 1 zones resist liquid penetration per AATCC (American Association of Textile Chemist and Colorist) 42:2000 with an AQL (acceptable quality level) of 4%. Level 4 critical zones resist liquid and viral penetration. The Stryker Steri-Shield Flyte Toga Zippered garment was tested for resistance to bacteriophage Phi-X174 in accordance with ASTM (American Society for Testing and Materials) F1671:2003 with an AQL of 4% under Procedure A. The barrier material for the Stryker Steri-Shield Flyte Toga Pullover is constructed of layers of polypropylene or polyester non-woven fabric and copolymer polyester film. The Stryker Steri-Shield Flyte Toga, Pullover will be available in a variety of sizes ranging from Small/Medium thru 3X-Large sizes.

Stryker Steri-Shield Flyte Toga, Zippered; Stryker Steri-Shield Flyte Toga with Peel-away Lens, Zippered; Stryker Steri-Shield Flyte Toga with UV Lens, Zippered.

The Stryker Steri-Shield Flyte Toga, Zippered; Stryker Steri-Shield Flyte Toga with Peel-away Lens, Zippered; and Stryker Steri-Shield Flyte Togas with UV Lens, Zippered are intended to be worn over any Stryker Flyte Helmet. The Stryker Steri-Shield Flyte Togas provide protection as specified by the AAMI (Association for the Advancement of Medical Instrumentation) Barrier Classification System. Level 1 zones resist liquid penetration per AATCC (American Association of Textile Chemist and Colorist) 42:2000 with an AQL (acceptable quality level) of 4%. Level 4 critical zones resist liquid and viral penetration. The Stryker Steri-Shield Flyte Toga Zippered garment was tested for resistance to bacteriophage Phi-X174 in accordance with ASTM (American Society for Testing and Materials) F1671:2003 with an AQL of 4% under Procedure A. The Level 4 barrier material is constructed of layers of polypropylene or polyester non-woven fabric and copolymer polyester film. The Level 1 material on the back of the zippered togas is constructed of 35 gram SMMS polypropylene. The Stryker Steri-Shield Flyte Toga, Zippered will be available in a variety of sizes ranging from Small/Medium thru 3X-Large sizes.

Indications for Use: The Stryker Steri-Shield Flyte Togas are components of a personal protection system and are intended to protect the patient, health care personnel and operating room personnel against

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contamination, exposure of infectious bodily fluids, the transfer of microorganisms and particulate material.

Substantial Equivalence (SE) Rational:

The Stryker Steri-Shield Flyte Togas are substantially equivalent to devices in commercial distribution.

Stryker Steri-Shield Flyte Togas have an equivalent intended use, patient contact materials, operating principles and physical specifications as compared to predicate devices.

Safety and Effectiveness:

Based upon the comparison to the predicate devices, the Stryke Steri-Shield Flyte Togas are substantially equivalent to legally marketed devices. The Stryker Steri-Shield Flyte Togas do not raise any new safety or efficacy concerns.

Submitted by:

Paulette D. Johnson
Regulatory Analyst
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, MI 49009
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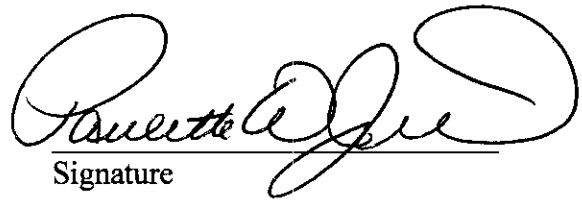

Signature

Date Submitted: 10-18-07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2007

Ms. Paulette D. Johnson
Regulatory Analyst
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K073017
Trade/Device Name: Stryker Steri-Shield Flyte Togas
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: November 19, 2007
Received: November 20, 2007

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073017

Device Name: **Stryker Steri-Shield Flyte Togas** (Stryker Steri-Shield Flyte Toga, Pullover; Stryker Steri-Shield Flyte Toga, Zippered; Stryker Steri-Shield Flyte Toga with Peel-away Lens, Zippered; and Stryker Steri-Shield Flyte Togas with UV Lens, Zippered)

Indications for Use:

The Stryker Steri-Shield Flyte Toga, Pullover; Stryker Steri-Shield Flyte Toga, Zippered; Stryker Steri-Shield Flyte Toga with Peel-away Lens, Zippered; and Stryker Steri-Shield Flyte Togas with UV Lens, Zippered are components of a personal protection system and are intended to protect the patient, health care personnel and operating room personnel against contamination, exposure of infectious bodily fluids, the transfer of microorganisms and particulate material.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073017